IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant-Appellant(s)	Cowley et al.	Examiner:	BRISTOL, LYNN ANNE
Serial No.:	10/511,794	Group Art Unit:	1643
Filed:	March 17, 2005	Docket:	976-20 PCT/US/RCE
Confirmation No:	6673	Dated:	September 22, 2009
For:	SPECIFIC ANTIBODY FRAGMENTS FOR THE HUMAN CARCINOEMBRYONIC ANTIGEN (CEA)		

Board of Patent Appeals and Interferences
United States Patent and Trademark Office
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REPLY BRIEF PURSUANT TO 37 C.F.R. §41.41

Sir:

Appellants submit herewith a Reply Brief in response to the Examiner's Answer mailed July 23, 2009, concerning the above-referenced application. The Reply Brief is being filed within two months from the mailing date. Accordingly, Appellants believe no fee is required. However, if any fees are due or any overpayment made in connection with this submission, please charge or credit our Deposit Account No.: 08-2461 for such sum.

ARGUMENT

Below, Appellants specifically address the following issues from the initial appeal brief:

1. Whether claims 32-36, 39-42, and 47-56 are unpatentable under 35 U.S.C. § 103(a) over Tormo (*APMIS* 97(12):1073-80 (1989)) in view of Freyre et al. (*J. Biotechnol.* 76:157-163 (2000)), as evidenced by Ayala et al. (*Conf. on Plant-made Pharmaceuticals 2005*; abstract), and Holliger et al. (*PNAS* 90:6444-6448 (1993)).

2. Whether the Ayala et al. (*Biotechniques* 13:790-799 (1992)) reference was previously cited during prosecution

Obviousness

Quoted on page 4 of the Examiner's Answer is the last sentence of 35 U.S.C. § 103(a): "Patentability shall not be negatived by the manner in which the invention was made." The Examiner's Answer fails to comply with the statute and fails to address Appellants' arguments regarding the lack of any disclosure and predictability in the combination of references concerning the claimed specific sequences.

In response to Appellants' assertions that the claimed fragments (i.e., compositions) are not predictable, the examiner relies on the allegation that "methods for making a scfv…were taught by Freyre," the CB/ior-CEA.1 hybridoma was known, and Freyre and Ayala allegedly provided "motivation to avoid introducing PCR

mutations."[1] In other words, the examiner asserts that a method of making an antibody fragment, a known hybridoma, and a general motivation to avoid mutations suffice to provide predictability concerning the synthetic antibody fragments comprising a specific sequence. Such reasoning is improper and irrelevant.

The examiner fails to take into account the limitations of the claims that require a specific sequence encoding a synthetic antibody fragment that is specific for human carcinoembryonic antigen. None of the cited references disclose any sequences whatsoever.

The examiner's emphasis on the availability of methods for producing an scFv by Freyre et al. and a motivation to avoid mutations misses the main point in an obviousness determination. Nothing in the cited references suggests that the method of Freyre would produce the claimed synthetic antibody fragments. In fact, Freyre et al. developed an scFv antibody fragment from the same hybridoma, CB/ior-CEA.1, yet failed to arrive at the claimed invention because their fragments contained mutations.[2]

Moreover, a motivation for obtaining a chemical composition free of mutations does not render the claimed invention obvious. The cited references merely provided a wish or plan to arrive at the claimed invention. They do not provide any disclosure of an identical or similar chemical structure to those required in the claims. Therefore, the cited references fail to obviate the claims.

[1] See pages 12 and 14 of the Examiner's Answer.
[2] See Appellants' brief on pages 12-13.

The Ayala et al. (*Biotechniques* 13:790-799 (1992)) reference was previously cited during prosecution

On page 4 of the Examiner's Answer, the examiner states, "Appellant has relied upon a reference incorporated in the specification in their Arguments that was not previously cited during prosecution," namely, Ayala et al. (*Biotechniques* 13:790-799 (1992)). In addition, on page 14 of the Examiner's Answer, the examiner states, "Appellants have not made reference to the prior art and anti-CEA antibody of Ayala et al. (*Biotechniques* 13:790-799 (1992)) described on p. 3 at lines 29-35 of the specification anywhere in the prosecution history and prior to filing their Appeal Brief."

Appellants respectfully disagree. On pages 7, 8, 10, and 11 of the Response to Advisory Action filed by Appellants on July 7, 2008, Appellants referred to the Ayala (1992) reference as it was described in the specification and in the Freyre (2000) reference. In the Response, Appellants specifically referred to passages in the specification and the Freyre reference that described the Ayala (1992) reference. Moreover, the examiner responded to Applicant's remarks concerning the Ayala (1992) reference on page 6 of the Office Action mailed October 9, 2008. Accordingly, contrary to the statement made in the Examiner's Answer, Appellants have made reference to the Ayala (1992) article in the prosecution history.

Conclusion

For the foregoing reasons and those set forth in Appellant's appeal brief, Appellants respectfully request reversal of the rejections contained in the Office Action of October 9, 2008.

Respectfully submitted,

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